

<b>TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371</b>		ATTORNEY'S DOCKET NUMBER C0875.70019US02
INTERNATIONAL APPLICATION NO. PCT/US2004/030813		INTERNATIONAL FILING DATE 20 September 2004 (20.09.2004)
TITLE OF INVENTION TREATMENT OF SEVERE DISTAL COLITIS		U.S. APPLICATION NO. (If known, see 37 CFR 1.5) <b>10/572667</b> PRIORITY DATE CLAIMED 18 September 2003 (18.09.2003)
APPLICANT(S) FOR DO/EO/US RUFO, Paul A.; LENCER, Wayne I.		

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
  - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☒ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Forms PCT/IB/301/304/308; PCT Published Application; International Search Report/ISA Opinion

Express Mail No: EV716303958US

U.S. APPLICATION NO. <b>10/572667</b>		INTERNATIONAL APPLICATION NO. PCT/US2004/030813		ATTORNEY'S DOCKET NUMBER: C0875.70019US02	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21.	<input checked="" type="checkbox"/>	Basic national fee (37 CFR 1.492(a)).....	\$300	\$ 300.00	
22.	<input checked="" type="checkbox"/>	Examination fee (37 CFR 1.492(c))			
If the written opinion prepared by the ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....					
All other situations .....				\$ 200.00	
23.	<input checked="" type="checkbox"/>	Search fee (37 CFR 1.492(b))			
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4) .....					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority .....				\$100	
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB .....				\$400	
All other situations .....				\$500	
TOTAL OF 21, 22 and 23 =				\$ 600.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	44 - 20 =	22	x 50.00	\$ 1100.00	
Independent claims	3 - 3 =	0	x 200.00	\$	
MULTIPLE DEPENDENT CLAIM(s) (if applicable)				\$ + 360.00	
TOTAL OF ABOVE CALCULATIONS =				\$ 1700.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL =				\$ 1700.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				\$ +	
TOTAL NATIONAL FEE =				\$ 1700.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				\$ +	
TOTAL FEES ENCLOSED =				\$ 1700.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ 1700.00 to cover the above fees is enclosed. b. <input type="checkbox"/> Please charge my Deposit Account No. 23/2825 in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed. c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 23/2825. A duplicate copy of this sheet is enclosed. d. <input type="checkbox"/> Fees are to be charged to a credit card. <b>WARNING:</b> Information on this form may become public. <b>Credit card information should not be included on this form.</b> Provide credit card information and authorization on PTO-2038.					
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status. SEND ALL CORRESPONDENCE TO: Wolf, Greenfield & Sacks, P.C. 600 Atlantic Avenue Boston, Massachusetts 02210-2206 Tel. (617) 646-8000					
CUSTOMER NUMBER:			<b>23628</b>		
			SIGNATURE: <i>Edward R. Gates</i>		
			NAME: Edward R. Gates		
			31,616		
			REGISTRATION NUMBER		

## Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV 716303958 US in an envelope addressed to:

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

on MARCH 20, 2006  
Date

Edward R. Gates  
Signature

Edward R. Gates

Typed or printed name of person signing Certificate

31,616

Registration Number, if applicable

(617) 646-8232

Telephone Number

Note: Each paper must have its own certificate of mailing, or this certificate must identify each submitted paper.

Transmittal Letter to the United States Designated/Elected Office (2 pages)  
Application (37 pages)  
Claims (5 pages – 44 claims)  
Abstract (1 page)  
Drawings (8 pages – Figs 1-8)  
Application Data Sheet (2 pages)  
First Preliminary Amendment (7 pages)  
Forms PCT/IB/301;304;308, ISR/ISA Opinion  
Return Receipt Postcard